

# Acupuncture for Lower Back Pain

## A Review

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**Objective:** We briefly discuss the history of acupuncture and its postulated mechanisms of action, but our primary objective is to discuss the evidence for acupuncture's efficacy in low back pain as well as approaches of newer study protocols to define more clearly the true usefulness of this alternative modality in low back pain.

**Methods:** Pubmed online search of all articles and other literature in the past 50 years related to acupuncture efficacy in low back pain, including case reports, randomized controlled trials and meta-analyses.

**Results:** Lower back pain and its associated incapacitating sequelae constitute an important healthcare and socioeconomic problem. There have been multiple, generally poor quality studies on the efficacy of acupuncture for this multi-factorial pain condition. Although newer studies seem to show promise, effectiveness has not been clearly demonstrated.

**Conclusions:** There is a paucity of high-quality research assessing efficacy of acupuncture in the management of LBP. Nonetheless, it continues to play a significant role in our clinical practice, not as a sole therapeutic modality but rather as an adjunct to a multi-disciplinary integrative approach of LBP management. Most of the published articles about acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess its efficacy. Thus it is imperative that further research be performed, both preclinical to help elucidate the mechanisms underlying acupuncture, and clinical to justify its clinical application.

**Key Words:** acupuncture, acupuncture research, efficacy, low back pain, treatment

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Low back pain (LBP) affects men and women equally, with onset most often between the ages of 30 and 50 years.<sup>1</sup> It is the most common cause of work-related disability in people under 45 years of age, and the most expensive cause of work-related disability, in terms of workers' compensation and medical expenses. Eighty percent of people will have at least 1 episode of LBP during their lifetime, and LBP affects a reported 5.6% of US adults each day.<sup>2</sup> In terms of healthcare expense, it is estimated that LBP costs the United States \$25 billion

annually, possibly over \$100 billion if overall costs are taken into account. A significant portion of treatment costs for conventional Western medicine encompass interventional spine injections, workman's compensation, lost hours/manpower, and pharmaceuticals and their side effects. On the other hand, German state insurance plans spend roughly 250 million Euros annually on acupuncture.

In nonspecific LBP, 90% seen within 3 days of onset recover within 4 weeks.<sup>3</sup> A third of patients are substantially improved at 1 week and two-thirds are fully recovered by 7 weeks. Unfortunately, recurrences are common, affecting 40% of patients within 6 months. In terms of disk herniations, only about 10% of patients have sufficient pain after 6 weeks that surgery is considered. Spinal stenosis usually remains stable or gradually worsens: 15% improve over 4 years, 70% remain stable, and 15% have deterioration. LBP thus is a chronic problem with intermittent exacerbations, rather than an acute disease that can be cured.<sup>3</sup>

Conventional treatment encompasses physical therapy, heat therapy, spinal manipulation, cognitive-behavioral therapy, biofeedback, self-care education, nonsteroidal anti-inflammatory drugs, muscle relaxants, antidepressants, anticonvulsants, and opioids. Additionally selective nerve blocks, epidural steroid injections, and spinal cord stimulators, for LBP associated with radiculopathy are used. Weight loss and smoking cessation are always recommended. Surgery is resorted to as a final option in refractory cases. Despite all these emergent options, the outcome of LBP treatment with conventional modalities is rather disappointing, and the LBP patient population is increasingly turning to alternative medical therapies.

Use of acupuncture as an additional modality earlier in the treatment of LBP at the critical juncture of 4 to 6 weeks has been mooted as being more cost effective, and may improve back-to-work statistics. Ten percent of general practitioners in Great Britain refer patients for acupuncture or perform acupuncture themselves. Estimates of popular use of complementary and alternative medicine overall in the US adult population exceeds 40%, with acupuncture occupying a prominent portion.<sup>4</sup>

### HISTORY OF ACUPUNCTURE THROUGH ANCIENT AND MODERN TIMES

This tradition of healing can be traced back at least 3500 years (late Stone Age). According to acupuncture, there are invisible channels called meridians through which life energy circulates throughout the body. Theory holds that it is an imbalance of this life energy that results in disease and pain. The acupuncture points are the locations where the "Qi" or energy of the channels rises close to the surface of the body. By manually needling or stimulating these points, it is believed to allow for restoration of health. Traditional Chinese medicine (TCM) holds that there are

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over 2000 acupuncture points on the body, although some classic texts describe only 365. Other practices included in the TCM system include dietary approaches, herbalism, cupping, moxibustion (the heating of an acupuncture point or needle with a smoldering herb), massage, Tai Chi exercise, and meditation.

In the 14th century, due to reports from Marco Polo, and through the trade missions of England, Holland, and France in East Asia in the 17th century, acupuncture was introduced to Europe. It was applied in Europe for the first time around the 17th century, primarily in France and Germany, by Jesuit priests who had served as Catholic missionaries in the East.

During the 1950s in Europe and the United States, acupuncture reemerged in the West. The German Acupuncture Society was established in 1951. In 1972, the respected New York Times columnist James Reston underwent an emergency appendectomy while in China. He later wrote about acupuncture treatment for postoperative pain that was very successful. This report attracted attention and many American physicians and researchers went to China to observe and learn acupuncture techniques. In Britain, acupuncture in the last 20 years has been flourishing alongside other alternative and complementary medicines. In 1996, the Acupuncture Society was recognized by the London Local Authorities under the London Local Authorities Act of 1991 to further the development of Acupuncture and Chinese Herbal Medicine in Britain alongside many other Chinese and British societies, associations, and schools. In Northern America, chiropractors, along with other healthcare professionals, are using acupuncture as an adjunct to their main therapeutic intervention, as demonstrated by a recent survey by the Canadian Chiropractic Protective Association.

In the late 1970s, the World Health Organization recognized the ability of acupuncture and Oriental medicine to treat nearly 4 dozen common ailments, including neuromusculoskeletal conditions (such as arthritis, neuralgia, insomnia, dizziness, and neck/shoulder pain); emotional and psychological disorders; addictions; respiratory disorders; and gastrointestinal conditions.<sup>5</sup> Their list of conditions can be accessed at <http://tcm.health-info.org/WHO-treatment-list.htm>.

In 1996, the Food and Drug Administration relabeled acupuncture needles as medical equipment and no longer as experimental devices. The NIH Consensus Panel: Acupuncture 1997 found that acupuncture could be useful by itself or in combination with other therapies to treat addiction, headaches, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, LBP, carpal tunnel syndrome, and asthma. However, acupuncture was only proven to be evidence-based for 2 indications: dental pain and nausea (postsurgical, chemotherapy induced, and related to pregnancy). They concluded that it was time to take acupuncture seriously but that better-designed studies were needed to confirm its utility in these other areas. This consensus statement is available at [http://consensus.nih.gov/cons/107/107\\_intro.htm](http://consensus.nih.gov/cons/107/107_intro.htm). Widespread acceptance and integration are still far from realized though, especially in the United States.

### POSTULATED MECHANISMS OF ACTION

It is indeed perplexing to both lay people and healthcare practitioners how a relatively small dry needle

(acupuncture needle) inserted at a site distant from its desired application can work (eg, a point on the lower leg affecting the stomach or a point on the arm affecting the heart). Consequently skeptics claim that the mechanism of action of acupuncture is based on its a placebo effect as the acupuncture meridians and their energy chi (Qi) as commonly described in eastern medicine cannot be dissected or measured, using standard anatomic, or physiologic approaches. One of the main argument against a placebo effect is the fact that acupuncture has been used successfully in animals,<sup>6</sup> which seems to disprove the placebo theory. Further, placing an emphasis on the needle and the physical effect of its insertion into the skin is not essential according to some reports.<sup>7</sup> Nonetheless, it is safe to say that lack of acceptance of acupuncture is due to primarily to a combination of poor understanding of known mechanisms as well as lack of proven published efficacy and limited exposure and training in complementary therapy in traditional medical training. Some of the suggested mechanisms based on Western medicine research are briefly discussed below.

### Endorphin Hypothesis

This theory suggests that stimulation of A-delta afferents by appropriate needling induces a cascade of endorphins, enkephalins, dynorphin, and monoamine transmitters active in spinal, midbrain, hypothalamic, and pituitary sites.<sup>8</sup> Evidence to support this comes from several human and animal studies. Manipulation of a needle in the acupoint of volunteers produced a slow increase of the skin pain threshold, followed by an exponential decay after removal of the needle.<sup>9</sup> A cerebrospinal fluid cross-infusion study from a rabbit subjected to acupuncture stimulation and infused into the third ventricle of a naive recipient rabbit, showed transference of the analgesic effect from the donor to recipient rabbit.<sup>10</sup> Opium addicts who underwent acupuncture analgesia for surgery were noted not to go through narcotic withdrawal compared with similar patients who received conventional anesthesia.<sup>11</sup> Several studies found release of endogenous opioid peptides<sup>12</sup> after acupuncture treatments. Electroacupuncture (EA) has been found to induce release of neurotransmitters such as enkephalins and dynorphin and substance P<sup>13</sup> in the central nervous system (CNS).

Acupuncture-induced analgesia can be blocked by naloxone in both humans and mice. Naloxone can only block the analgesic effect induced by EA of low frequency (4 Hz), but not that of high frequency (200 Hz), suggesting that low-frequency rather than high-frequency stimulation triggers the release of opioid peptides.<sup>11</sup> However, a paper of Han's<sup>14</sup> found that both low-frequency and high-frequency EA analgesia were reversible but the ID<sub>50</sub> of naloxone for blockade of the analgesic effect produced by 2, 15, and 100 Hz EA analgesia was found to be 0.5, 1.0, and 20 mg/kg. This result suggested that the analgesia induced by 2 Hz EA was mediated by the mu receptor and that of 100 Hz EA by kappa opioid receptors. Han's study further demonstrated that different frequencies of stimulation can facilitate differential release of different brain neuropeptides.<sup>14</sup> An additional animal study showed that repeated EA stimulation has cumulative therapeutic effect on chronic pain. It suggested that EA analgesia and morphine analgesia share similar mechanisms.<sup>15</sup> Another study has shown that a proper combination of different frequencies may produce a maximal release of a cocktail of

neuropeptides for better therapeutic effects.<sup>16</sup> A very recent paper by Staud<sup>17</sup> states that as acupuncture-related pain relief takes considerable time to develop and resolve, some of its long-term effects cannot be explained by placebo mechanisms, and EA seems best to activate powerful opioid and nonopioid analgesic mechanisms. A recent systematic review has confirmed that the placebo effect is mediated via endogenous opioids. Therefore it may be difficult to delineate the placebo effect from the acupuncture effect, as both treatments seem to share common pathways in analgesia.<sup>18</sup>

### Neurophysiologic Theory

This school of thought defines acupuncture points on “a roughly dermatomal basis; partially involving long reflexes to distant parts of the body, which implicates a distribution by specific spinal segments or nerves; and are partially via unknown connections.<sup>19</sup> This could explain remote stimulation, but as the quote suggests, it is a very incomplete explanation. However, a very recent excellent study by Inoue et al<sup>20</sup> demonstrated another physiologic explanation, namely, there was far better and immediate relief when EA was applied to the sciatic nerve root, rather than to lumbar muscle or pudendal nerve in patients with lumbar spinal stenosis and herniated lumbar disks. They then confirmed via laser-Doppler flow meter an increase in sciatic nerve blood flow of 100% with nerve root EA versus 56.9% with lumbar muscle EA. They concluded that in addition to acupuncture’s influence on pain inhibitory systems, that it also participates in causing transient changes in nerve blood flow, including circulation in the cauda equina as well as nerve roots. Nonetheless, it is not clear that the pain relief is the result of changes in blood flow. This needs to be investigated further.

### Neurohormonal Theory

This postulates release of neurohormones by needle insertion. There seems to be a marked difference in sex distribution of response to acupuncture, which is statistically significant. Women seem to respond far more than men. It is hypothesized that this phenomenon may be linked to estrogen receptors in the CNS.<sup>13</sup> Measurements of adrenocorticotrophic hormone have been shown to be elevated after acupuncture treatments, suggesting that adrenal activation and release of endogenous corticosteroids may also result from acupuncture.<sup>21</sup>

### Neurogate Theory

According to this theory, the stimulation of large diameter touch fibers by acupuncture needles could inhibit the small diameter inputs to the spinal cord, including pain. One type of sensory input (LBP) could be inhibited in the CNS by another type of input (needling). Nociceptive stimulation, such as with a transcutaneous electrical nerve stimulation unit, is known to block pain perception, supporting the neurogate theory. The same needling sensation has also been suggested to activate 2 descending neuronal mechanisms. The first of these is serotonergic and the second noradrenergic.<sup>22,23</sup>

### Diffuse Noxious Inhibitory Control Theory

This theory implies that noxious stimulation of heterotopic body areas modulates the pain sensation in areas where a participant feels pain.<sup>24</sup> This may involve activation of the propriospinal heterosegmental antinociceptive system leading to wind-down of pain-induced

changes in signal transduction in the spinal cord. An interesting study involved the injection of Technetium<sup>99</sup>, a radioactive tracer, into both sham and true acupoints. The scan of the injection sites showed random diffusion of the tracer around sham points, but rapid progression of the tracer along the meridian with true acupuncture, at a rate that was inconsistent with either vascular/lymphatic flow or nerve conduction.<sup>25</sup> Serotonin (5-HT) is thought most important among classic neurotransmitters for the mediation of acupuncture analgesia by 1 study.<sup>26</sup> Acetylcholine is additionally released.

A recent study<sup>27</sup> found increased nitric oxide synthase activity in meridians and acupoints. This involved a randomized, double-blind, crossover study with 20 volunteers, each of whom underwent 1 session each of real and noninvasive sham acupuncture in a single hand and forearm with a week interval between treatments. Both nitric oxide concentration and blood flow were increased in the acupuncture arm, and the latter correlated with the nitric oxide increase. These changes were not observed in noninvasive sham acupuncture hands and forearms. Because nitric oxide is a key regulator of local circulation, and because change in circulation can affect the development and persistence of pain, this article proposed that acupuncture might regulate nitric oxide levels.

Heat combined with acupuncture seems to be more effective than electropuncture alone.<sup>28</sup> The thermal effect produced by electrical heat acupuncture may produce additional antinociceptive effects on endorphinergic pain modulation than needle acupuncture alone. Heat can also increase the local circulation and remove chemical substances such as histamine, bradykinin, and prostaglandin released by chronic inflammation, which stimulate or sensitize the surrounding nociceptors.<sup>29</sup>

### Activation of Descending Inhibitory Pain Control Systems

Wu et al<sup>30</sup> characterized the CNS pathway for acupuncture stimulation in the human brain using functional magnetic resonance imaging. They demonstrated that acupuncture performed at Li-4 and ST.36 acupoints (both known to cause analgesia) activates descending antinociceptive pathways (hypothalamus and nucleus accumbens), and deactivates multiple limbic areas subserving pain association. Control stimulations at nonacupuncture points did not result in such activations and deactivations. There are numerous studies demonstrating a broad cerebral response to analgesic acupuncture involving the limbic system and limbic-related brain structures, including the hippocampus, hypothalamus, nucleus accumbens, cingulate, insular cortices, cerebellum, caudate, and putamen. Needling a point on the lower leg traditionally associated with the eye activated the occipital cortex of the brain as detected by functional magnetic resonance imaging.<sup>31</sup> Another excellent study by Schlunzen et al<sup>32</sup> showed that needle stimulation of L1-4 influenced the putamen. It compared regional cerebral blood flow in anesthetized patients exposed to manual acupuncture stimulation of L1-4 or a placebo point in the space between third and fourth metacarpals. A radioactive tracer was used. The group receiving placebo showed a decrease in regional cerebral blood flow in the right medial frontal gyrus, with no significant changes in the putamen. Those receiving acupuncture in L1-4 showed significant decrease

in regional blood flow in both the right medial frontal gyrus as well as the left putamen.

Last but not least, there are obviously psychologic aspects involved. Some physics concepts have also been postulated such as quantum physics, electromagnetic force field changes, and wave phenomena to account for some of the nonlocal effects of acupuncture. According to the National Institutes of Health, there is also evidence that stimulating acupuncture points enables electromagnetic signals to be relayed at a greater rate than under normal conditions. This may increase the flow of natural healing or painrelieving chemicals to injured areas.

In summary, the phenomenon of acupuncture has attracted the interest of basic scientists and clinicians from various disciplines, which has resulted in the above described hypotheses. It is obvious that the complexity of the mechanism of action can not be explained by a single hypothesis but rather a combination of the above hypotheses might be responsible for its mechanism of actions.

### EVIDENCE OF EFFICACY

In an era of increasing demands for evidence-based practice and professional accountability, practitioners using acupuncture for patients in Western countries may find themselves placed in a difficult position, which is possibly vulnerable to litigation. However, we are not aware of any documented litigation cases in the United States thus far. There is an urgent need for strong, scientifically sound studies on the true efficacy of acupuncture for LBP.

The evidence for the benefit of acupuncture is conflicting, with higher-quality trials showing moderate evidence that there is no benefit (see tables), but there are numerous uncontrolled case histories with beneficial out-

comes espousing the efficacy of acupuncture. The majority of these studies are of inadequate power. There are also some newer more rigorous randomized control trials in the past 5 years supporting a stronger role for acupuncture as an adjunctive modality for chronic LBP.<sup>33,34</sup> A study by Lewith and Machin<sup>35</sup> estimated that where true acupuncture may give 70% relief of pain, sham acupuncture may produce 50% relief, and placebo 30%.

For the first time in a recent study it has been shown that there is a broad consistency in fundamental aspects of Chinese acupuncture for chronic LBP across different kinds of practitioners and different countries. The data can be used as minimal standards for the design and funding of future clinical trials.<sup>36</sup>

A 1997 NIH Consensus Development Statement described acupuncture as a reasonable alternative treatment for LBP. However, in a study analysis of a longitudinal prospective cohort study from 2006 Chenot et al,<sup>37</sup> found that receiving acupuncture did not offset the use of other healthcare resources. In fact, it was associated with increased general practitioner consultation rates, specialist consultations, and prescriptions for physiotherapy. Acupuncture patients were also more likely to receive other controversial treatment options like manual therapy, transcutaneous electrical nerve stimulation, and injection therapies. A significant proportion of patients who received acupuncture did not meet the only known selection criterion chronicity. This study concluded that acupuncture therapy might be a reflection of helplessness in both patients and healthcare providers.

Patients who have not undertaken any previous form of conservative treatment have been found to respond best to acupuncture treatment.<sup>38</sup> Acupuncture may also shorten the period of hyperacute symptoms, and thus possibly the need for more invasive treatments.<sup>39</sup> Similarly, conditions

**TABLE 1.** Summary of Meta-analysis Studies Evaluating Acupuncture Treatment for LBP

Study Year (Ref.)	Type of LBP	No. RCTs Evaluated	No. Patients Completing the Study	Acupuncture Points Used	Frequency of Acupuncture Treatment	Outcome
Ernst and White <sup>42</sup>	Chronic axial, failed back surgery	12	377	Conventional and trigger point	8 sessions over 10 wk, or 1 session a week over 4-10 wk	Odds ratio of improvement 2.30 favoring acupuncture even in those cLBP with poor prognosis such as failed back surgery patients
Cherkin et al <sup>43</sup>	Nonspecific LBP	20	No specified total but > 500	Various traditional Chinese acupoints	Approximately 8 sessions over 10 wk	Acupuncture less effective than massage for LBP, its effectiveness remains unclear
Manheimer et al <sup>44</sup>	Acute and chronic LBP	33	2621	Chinese and Western	1-18 sessions 1-5 times a week	Effective pain relief, acupuncture may be superior to sham, but no more effective than other therapies
Furlan et al <sup>45</sup>	Nonspecific subacute, or chronic LBP, or myofascial LBP	35	2861	Classic meridian points, extra points, or ah-shi points, myofascial trigger points	Variable	Pain relief and functional improvement for acupuncture compared with sham or no treatment. Effects small. May be better results if added to conventional therapy rather than these alone. Similar to other conventional treatments

LBP indicates low back pain; cLBP, chronic low back pain.

where spasm is present are those that respond most favorably to acupuncture.<sup>40</sup> Results of acupuncture after laminectomy are better than those after spinal fusion. There is also a relationship between the number of acupuncture treatments and the onset of symptomatic relief. A recent study showed that acupuncture had a long-term effect on important aspects of cognitive and emotional pain coping.<sup>41</sup>

A summary of most current meta-analysis articles is presented in Table 1. The most important meta-analysis is possibly that by the Cochrane Collaboration in 2007. It looked at 35 RCTs from 1996 to 2003 examining acupuncture in adults with nonspecific subacute or chronic LBP, or dry needling for myofascial pain syndrome in the low back region.<sup>45</sup> It concluded that acupuncture, added to other conventional therapies, relieved pain, and improved

function better than the conventional therapies alone. However, this effect was small, and acupuncture was not more effective than other conventional and “alternative” treatments. Dry needling seemed to be a similarly effective adjunct. The authors could not make clear recommendations. The RCTs that were included used at least 1 of the 4 outcome measures considered to be important in the field of LBP: pain intensity, a global measure like overall improvement or subjective improvement of symptoms, back-specific functional status, and return to work. The primary outcomes for this review were pain and functional status.

A recent review looking at 33 randomized controlled trials (RCTs), found that acupuncture was more effective than sham treatment for short-term relief of chronic LBP. However, for acute LBP, data are sparse and inconclusive, and also insufficient for drawing conclusions about

**TABLE 2.** Randomized Control Trials Evaluating Acupuncture Treatment for LBP

Study Year (Ref.)	Type of LBP	No. Patients Completing the Study	Acupuncture Points Used	Frequency of Acupuncture Treatment	Outcome
Carlsson and Sjolund <sup>47</sup>	Chronic axial LBP	50	Manual and electroacupuncture acupoints	Once a week for 8 wk	Significant improvement in pain ( $P < 0.05$ ) sleep, return to work, analgesic use and function for needle acupuncture versus true placebo at 1, 3, and 6 mo
Leibing et al <sup>48</sup>	Chronic axial LBP	131	Traditional body and extra <sup>6,20</sup>	20 sessions over 12 wk- 5 × a week for 2 weeks, then 1 × a week for 10 wk	Acupuncture more effective than physiotherapy but not sham acupuncture, so acupuncture has a placebo effect
Molsberger et al <sup>49</sup>	Axial LBP	186	Standard AP points + 4 additional	12 treatment sessions over 4 wk	Acupuncture can be a good supplement to other conservative therapy
Sator-Katzenschlager et al <sup>33</sup>	Chronic axial LBP lumbar/lumbosacral	61	Auricular points 29, 40, 55	Once a week for 6 wk	Auricular electroacupuncture relieves chronic LBP more effectively than conventional manual acupuncture
Meng et al <sup>50</sup>	Chronic axial LBP	47	10 standard local AP points + 4 additional	Twice a week for 5 wk	Acupuncture is effective and safe as an adjunctive modality
Yeung et al <sup>51</sup>	Chronic nonspecific axial LBP	52	electroacupuncture UB 25, UB40, SP6	3 times a week for 4 wk	Combination of acupuncture with exercise better than back exercises alone for both function and pain relief
Brinkhaus et al <sup>52</sup>	Chronic axial LBP	298	Local/distant points + extraordinary points, some ear + trigger points	12 sessions over 8 wk	Acupuncture improves pain compared with no therapy but no significant differences between acupuncture versus minimally invasive acupuncture
Thomas et al <sup>53</sup>	Nonspecific axial LBP 4-52 weeks duration	241	Traditional acupuncture points	10 sessions over 3 mo	Weak positive evidence in favor of acupuncture for pain relief only in LBP at 12 mo but stronger evidence of a small benefit at 24 mo. No change to functional disability
Brinkhaus et al <sup>54</sup>	Chronic LBP, axial	300	Multicenter observational, variety of AP points	8 sessions on average	Acupuncture more effective than sham acupuncture, even when used as a single modality in short-term therapy

AP indicates acupuncture; LBP, low back pain.

acupuncture's short-term effectiveness compared with most other therapies.<sup>44</sup> This concurred with the meta-analysis from 1998 that showed an overall odds ratio of improvement of 2.30 favoring acupuncture treatments.<sup>42</sup> This meta-analysis also showed that acupuncture is more effective than sham acupuncture for short-term pain relief, as did the study by van Tulder et al in 2005.<sup>46</sup> Thus, there is insufficient evidence to recommend acupuncture in acute LBP.

A summary of RCTs is presented in Table 2. An RCT from 2006 with 298 patients<sup>52</sup> showed that acupuncture was more effective in improving pain than no acupuncture treatment in chronic LBP, but that there were no significant differences between deep acupuncture and minimally invasive acupuncture. This was one of the largest and most rigorous trials to date, using central randomization, assessment of the credibility of interventions, interventions based on expert consensus provided by qualified and experienced medical acupuncturists, and high follow-up rates.

On the other hand, a large RCT to evaluate acupuncture was recently published by Cherkin et al.<sup>54</sup> After an average of 8 treatments of over a 10-week period, TCM acupuncture was found less effective than therapeutic massage, but equivalent to self-care education, in decreasing pain and increasing function. Additionally, after 1 year, those originally treated with acupuncture had worse pain and dysfunction than those in the massage group.

A randomized, blinded, placebo-controlled trial from Germany with 131 patients where all patients received active physiotherapy over 12 weeks and control versus acupuncture and sham acupuncture groups were compared, showed significant improvement by traditional acupuncture in chronic LBP compared with physiotherapy, but not compared with sham acupuncture. Their conclusion was that the trial demonstrated a placebo effect of traditional acupuncture in chronic LBP.<sup>48</sup>

A randomized study by Ga et al<sup>55</sup> in 39 patients comparing acupuncture needling and 0.5% lidocaine injection of trigger points for treating myofascial pain syndrome in elderly patients showed no significant difference, although both groups improved. Deep needling to trigger points has been found to be more effective than either standard acupuncture therapy or superficial needling to trigger points.<sup>56</sup>

Results of a new study by Cherkin et al<sup>54</sup> discussed in Trials February 2008 had a total of 640 participants, and tried to address some of the methodologic shortcomings of previous studies on LBP and acupuncture. It will randomize patients to 1 of 2 forms of TCM acupuncture needling (individualized or standardized), have a control group (simulated acupuncture) and a group with usual medical care. The primary analysis will compare outcomes by randomized treatment assignment by analysis of covariance adjusted for baseline value. This trial will have

**TABLE 3.** Clinical Studies (Observational and Other Types) Evaluating Acupuncture Treatment for LBP

Study Year (Ref.)	Type of LBP	Type of Studies	No. Patients Completing the Study	Acupuncture Points Used	Frequency of Acupuncture Treatment	Outcome
Longworth and McCarthy <sup>38</sup>	Chronic LBP secondary to DDD, sciatica	Review of 13 trials	Specific numbers not given	Not stated	Not stated	May be a role for acupuncture, not just for pain relief. It may reduce the requirement for more invasive forms of therapy
Kukuk et al <sup>40</sup>	Chronic axial LBP	Prospective cohort	249	Not stated	Once a week for 10 wk	Pain tolerability was significantly improved after acupuncture and remained so up to 6 months after therapy. It has therefore long-term effects on cognitive and emotional pain coping
Itoh and Kitakoji <sup>59</sup>	Axial LBP	Review of 57 trials	Number not stated	Varying standard traditional + trigger points	Not stated	Limited evidence that AP is more effective than any rx; inconclusive evidence that AP more effective than placebo, standard care, sham acupuncture
Prady et al <sup>60</sup>	Axial LBP, chronic	Observational questionnaire	102	Not stated in article	Not stated	Acupuncture speeds recovery from a back pain episode, improvements plateau after 2 y
Weidenhammer et al <sup>58</sup>	LBP nonspecific, chronic axial	Prospective observational, multicenter	2564	Unknown, not stated	8 sessions—15 AP sessions plus other treatments for example, drugs, PT	Acupuncture is safe, patients benefited from the treatment Effectiveness rated by physicians in 22% marked, 54% moderate, 16% minimal, 4% as poor (unchanged) 45% patients demonstrated clinically significant improvements in their functional ability scores. Effect size 0.96

AP indicates acupuncture; DDD, degenerative disc disease; LBP, low back pain; PT, physical therapy; rx, therapy.

99% power to detect the presence of a minimal clinically significant difference amongst all 4 treatment groups, and over 80% power for most pair wise comparisons. This will be an important trial to clarify the value of acupuncture needling as a treatment for chronic LBP. A further two large RCTs in the United Kingdom and Germany<sup>57,58</sup> concur with the protocols and design, and have multidisciplinary center involvement. The German study showed positive results for acupuncture, if a semi-standardized acupuncture strategy is used.

Another interesting randomized, double-blind, controlled study tested the hypothesis that auricular electroacupuncture (AEA) relieves pain more effectively than conventional manual acupuncture in people with chronic LBP.<sup>35</sup> It looked at a number of outcome parameters. All parameters showed significant improvement in group AEA versus conventional manual acupuncture, and furthermore, found that neuropathic pain in particular, improved in patients with AEA. These were the first results to demonstrate that continuous AEA stimulation of auricular acupuncture points improved chronic LBP in an outpatient population.

Some other important miscellaneous studies including retrospective and observational studies are summarized in Table 3. A recent review looking at 11 different articles consisting of 3 case studies, 5 randomized controlled trials, and 2 cross-over trials, did not provide definitive evidence to support or refute the use of acupuncture in the treatment of LBP.<sup>61</sup>

There are numerous small cohort studies and case reports throughout the literature attesting to the effectiveness of acupuncture. These tend to show that modalities primarily focused on the back musculature (acupuncture, massage, physical therapy) are more effective with respect to functional capacity restoration. The improvements noted in 1 study<sup>62</sup> were predominantly in the nonsagittal planes of motion (lateral flexion and axial twist), which may reflect more complex restoration of the neuromuscular system within the lower back. Acupuncture significantly improved the short-term functional ability.

A multicenter observational study from Germany and Switzerland showed that acupuncture treatment is associated with clinically relevant improvements in patients reporting chronic LBP of varying degrees of chronification and/or severity, as well as patients with and without depression. This study was initiated by the German Federal Committee of Physicians and Statutory Sickness Funds in October 2000 and included both randomized trials and a large scale observational study. Over half a million patients between August 2001 and July 2003 participated. Variables of major interest were predefined to build a comprehensive profile of outcomes. However, it did not offer conclusive evidence regarding the extent to which the observed improvements were caused by acupuncture. Nonetheless, it did recommend acupuncture as a serious treatment option for chronic LBP.<sup>63</sup> Another observational study from Germany within the research program of 10 German health insurance funds published preliminary results December 2007.<sup>58</sup> This study included almost half a million patients with at least 3 chronic pain conditions including headache, LBP, and osteoarthritis. Acupuncture was a highly demanded option for chronic pain conditions, and their results indicated that acupuncture provided by qualified therapists was safe, and that patients benefited from the treatment.

## LIMITATIONS OF STUDIES

There have been several flaws with previous studies, which diminishes the value of the studies. Most of these problems are not unique to acupuncture and common for invasive pain procedures in general. Nonetheless, some of these flaws are:

- poor design with findings that are difficult to interpret due to limited power, too much heterogeneity; numbers of patients in the studies too small to be able to draw statistically significant conclusions; variation in diagnosis and treatment of LBP by traditional Chinese medicine acupuncturists. A study by Sherman et al<sup>64</sup> showed that TCM diagnoses and treatment recommendations vary widely across practitioners. Acupuncture points may be functionally interchangeable to some degree. They recommended comparison of individualized treatment with a thoughtfully developed standardized approach to see which, if either, is superior. Another study by Kalauokalani et al<sup>65</sup> of 7 TCM acupuncturists showed good concordance in diagnoses, but there was substantial variation in their treatment recommendations.
- inappropriate or inadequate treatment
- inappropriate comparison groups, or no controls at all
- lack of follow-up data
- poorly justified treatment with variability of inclusion and etiology of LBP, variety in type, location and duration of LBP, or sometimes the main outcome is not specific to acupuncture, or variability in outcomes measured
- variability in terms of duration of individual acupuncture sessions and duration of the intervention period
- patients with positive impressions of acupuncture had greater benefit from acupuncture compared with those with negative/neutral impressions and as such, either acupuncture naive patients only should be included in trials, and/or all participants for trials should be screened for their attitudes toward acupuncture efficacy and this be included in the statistical analysis. Recall bias is also a factor. A study last year showed that in patients with acute LBP, higher expectations for recovery are associated with greater functional improvement.<sup>66</sup> In contrast, general optimism about treatment, divorced from a specific treatment, is not strongly associated with outcome.
- lack of masking/blinding of participating physicians—however, this is impossible to avoid, as all studies have to be single blind
- inability to isolate the costs and effectiveness of individual treatments as part of the package of usual care.<sup>67</sup> It is well known and borne out by studies that there is some arbitrary use of complementary and alternative medicine by both patients and their providers.
- effects arising from regression to the mean; patients will tend to seek help at the point when the pain is at its worst or least bearable, and the clinical course of the condition is that the pain will reduce substantially for most people, with or without treatment.
- publication bias
- strong response to minimal acupuncture that cannot be considered an inert placebo. Sham acupuncture is a poor control for LBP as any needling may influence pain via diffuse noxious inhibitory control.
- there may be variation in terms of Chinese technique versus American acupuncture techniques as well as acupoints selected. In a study conducted in China with 56 patients with chronic LBP, the percentage of those who found relief was 98.3%.<sup>68</sup> However, TCM as currently taught and

practiced, shows considerable heterogeneity, even in China. Techniques range from needling methods with heavy stimulation to very light with multiple other variations being used.

- variability in experience and training of acupuncturists

Sherman and Cherkin<sup>69</sup> have discussed the rationale for and design of a 5 arm randomized controlled pilot clinical trial that will address the major methodologic shortcomings of previous studies. It will address the most important clinical questions in acupuncture research, namely:

- (1) is acupuncture treatment more effective than usual care alone?
- (2) is individualized acupuncture more effective than standardized acupuncture?
- (3) is there a 'specific effect' of acupuncture attributable to the needling procedure itself?
- (4) is needling of points that are considered helpful for a specific problem more effective than needling of acupoints not generally used for that problem?
- (5) is needling of acupoints considered ineffective for a particular condition more effective than noninsertive stimulation?

In summary, it remains unclear whether acupuncture is superior to placebo. For this reason, it is hard to draw any definitive conclusions from current data. It should also be noted also that for any therapeutic intervention, including acupuncture, the so-called nonspecific effects account for a substantial proportion of its effectiveness, and thus should not be casually discounted. Many factors may profoundly determine and confound therapeutic outcome findings including the quality of the relationship between the clinician and the patient, the degree of trust, the expectations of the patient, the compatibility of the backgrounds and belief systems of the clinician and the patient, as well as a myriad of other factors that together define the therapeutic milieu. All of these factors make acupuncture research validity in chronic LBP even more problematic. Further, there is also strong need for head-to-head comparisons between acupuncture and other interventions used for treating chronic LBP. Finally, currently, joint clinical practice guidelines from the American College of Physicians and the American Pain Society recommend that for patients who do not improve with self-care options like exercise and analgesics, clinicians should consider addition of nonpharmacologic therapy with proven benefits for subacute and chronic LBP like acupuncture, exercise therapy, spinal manipulation, yoga, cognitive-behavioral therapy, or progressive relaxation. They grade this as a weak recommendation, with moderate-quality evidence.<sup>70</sup>

## CONCLUSIONS

There is a paucity of high-quality research assessing efficacy of acupuncture in the management of LBP. Nonetheless, it continues to play a significant role in our clinical practice, not as a sole therapeutic modality but rather as an adjunct to a multidisciplinary integrative approach of LBP management. Most of the published articles about acupuncture in the biomedical literature consist of case reports, case series, or intervention studies with designs inadequate to assess its efficacy. Thus it is imperative that further research be performed, both preclinical to help elucidate the mechanisms underlying acupuncture and clinical to justify its clinical application.

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